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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention

[60Day-12-12GO]

Proposed Data Collections Submitted for  
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 and send comments to Kimberly S. Lane, at CDC 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

### **Proposed Project**

Colorectal Cancer Control Program Indirect/Non-Medical Cost Study – New – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung cancer. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons. Screening tests that may be used alone or in combination include fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, and/or colonoscopy.

While screening rates have increased over the past decade, screening prevalence is still lower than desirable, particularly

among individuals with low socioeconomic status. The indirect and non-medical costs associated with CRC screening, such as travel costs, may act as barriers to screening. Understanding these costs may provide insights that can be used to reduce such barriers and increase participation.

In 2005, CDC established a four-year demonstration program at five sites to screen low-income individuals aged 50-64 years who had no health insurance or inadequate health insurance for CRC. In 2009, by applying lessons learned from the demonstration program, CDC designed and initiated the larger population-based Colorectal Cancer Control Program (CRCCP) at 29 sites. The goals of the expanded program are to reduce health disparities in CRC screening, incidence and mortality by promoting CRC screening for the eligible population and providing CRC screening to low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

To date there has been no comprehensive assessment of all the costs associated with CRC screening, especially indirect and non-medical costs, incurred by the low-income population served by the CRCCP. CDC proposes to address this gap by collecting information from a subset of patients enrolled in the program.

Those who undergo screening by FIT or colonoscopy will be asked to complete a specialized questionnaire about the time and personal expense associated with their screening. Patients who undergo fecal immunochemical testing will be asked to complete the FIT questionnaire, which is estimated to take about 10 minutes. Patients who undergo colonoscopy will be asked to complete the Colonoscopy questionnaire, which includes additional questions about the preparation and recovery associated with this procedure. The estimated burden per response for the Colonoscopy questionnaire is 25 minutes. Demographic information will be collected from all patients who participate in the study. Participation in the study is voluntary, but patients will be offered an incentive in the form of a gift card.

CDC plans to conduct the information collection in partnership with providers in five states (Alabama, Arizona, Colorado, New York, and Pennsylvania). Each provider site will administer the survey until it reaches a target number of responses. Targets for each site range between 75 and 150 completed questionnaires, depending on the volume of patients screened. Each participating provider will make patient navigators available to assist patients with coordinating the screening process and completing the questionnaires. Providers will be reimbursed for

patient navigator time and administrative expense associated with data collection. Across the five participating sites, the estimated cost of this data collection is approximately \$50,000.

This information collection will be used to produce estimates of the personal costs incurred by patients who undergo CRC screening by FIT or colonoscopy, and to improve understanding of these costs as potential barriers to participation. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve delivery of CRC screening services and to increase screening rates among low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

OMB approval is requested for one year. Each respondent will have the option of completing a hardcopy questionnaire or an online questionnaire. No identifiable information will be collected by CDC or CDC's data collection contractor. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Type	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patients Served by the Colorectal Cancer Control Program	FIT questionnaire	300	1	10/60	50
	Colonoscopy questionnaire	315	1	25/60	131
	Total				181

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